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EXAMINER

STARSIK, JOHN S

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/295,691

Applicant(s)

Jon Faiz Kayyem

Examiner

J. STARSIAK

Group Art Unit

1753

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☒ Responsive to communication(s) filed on 02 May 2003
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 36-39, 45-47, 49, 50, 52, 53 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 36, 37, 45-47, 49, 50, and 53 is/are rejected.
- ☒ Claim(s) 38, 39, and 52 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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DETAILED ACTION

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 02 May 2003 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 to 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites "said detection module". This recitation does not have proper antecedent basis in claim 36. "Said detection module" appears to correspond to the "detection well" recited in claim 36. Claims 46 and 47 are rejected because they depend on claim 45.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 36, 37, 49, 50, and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Segal et al.

Segal et al teaches [col. 8, lines 47-53]: "In one embodiment, the diagnostic card device of the present invention includes the following elements which will be further described herein below: a support substrate, which includes a sample introduction region, a biosensor, a sample flow pathway communicating with said sample introduction region and said biosensor....". See Figures 8A and 16. Regarding claim 37 Segal et al. teaches {col. 11, lines 36-53]: "The devices can include, in conjunction with the sample introduction region, means for sample pretreatment, such as filters for red blood cells...The device can include a separation device for filtering the sample...Sample pretreatment can also...reduce or remove interfering substances such as immunochemical cross-reactants, redox substances and the like...". In other words, the reagent recited in claim 37 reads on the reagent(s) necessary to perform any of the sample pretreatment procedures recited by Segal et al. The detector elements recited in the above claims read on the

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several embodiments of biosensors of Segal et al., particularly the embodiment illustrated in figure 13 and described from col. 15, line 18 to col. 16, line 38. Regarding claims 49 and 50 Segal et al. teaches [col. 13, lines 15-18]: "Liquid sample migrates in the sample flow pathway by capillary action or is driven by a micro-pump or by electroosmotic flow induced by suitable placed electrodes. Regarding claim 53 Segal et al. teaches [col. 29, lines 7-9]: "Where the analyte-binding agent is a non-peptide moiety, e.g.,...nucleic acid..."

Allowable Subject Matter

Claims 38, 39, and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Segal et al. (the closest prior art) fails to explicitly disclose or fairly suggest: 1) filling sample introduction region 12 with a cell lysing agent; 2) placing a filter sample introduction region 12 and sample-flow pathway 38; 3) a valve positioned in sample-flow pathway 38.

Claims 45 to 47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Segal et al fails to explicitly disclose or fairly suggest a reaction module formed in the substrate 20 wherein microchannels connect said reaction module to the sample introduction region 12 and the biosensor module, respectively.

Response to Arguments

Applicant's arguments filed 02 May 2003 have been fully considered but they are not persuasive.

Applicant's declaration fails to overcome the rejection based upon Segal et al because the evidence presented fails to support applicant's argument that he possessed the "claimed subject matter" prior to Segal et al. First, exhibit 1 is merely a short list of handwritten notes (some parts of which are unreadable). While this exhibit discloses the general idea of combining the applicant's detector technology with a microfluidic device, it fails to support the detailed structure of the microfluidic device(s) recited in the claims. Exhibit 6 is suppose to illustrate a microfluidic device with an inlet, channel, and detection well. First, the copy of the photograph is so poor that none of this structure can be seen. Second, the structure of this microfluidic device does not correspond to the structure recited in the claims..


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700


John S. Starsiak Jr.

19 June 2003